Abstract: Recent scientific developments are changing knowledge about risks in the food supply and revolutionizing procedures for controlling those risks. New tests reveal that micro-organisms are a more common cause of foodborne disease than most Americans suspect. New data on widely used chemicals sometimes show levels of residues so low that they were formerly undetectable. Rapid tests may improve monitoring of the critical control points in food production and distribution. The improved testing could trigger legal restrictions. Many food safety policies were adopted before these testing improvements. The challenge is to incorporate this new knowledge into workable food safety policies that take into account the economic costs and benefits of such regulation.

Food Safety Regulations Under Review

Food safety regulations are being scrutinized as both our knowledge of foodborne risks expands and our ability to detect them improves. New scientific procedures increasingly allow food producers and health officials to detect and characterize food risk. Improved identification of contaminants provides new opportunities to control risks in the food supply. Many regulations have been enacted to assure the purity of the Nation's food supply. Even more are under consideration as a result of more sophisticated testing methods.

Potential effects of food contamination range from diarrhea to cancer and arise from a number of sources. Pathogenic (human disease-causing) microbes and environmental contaminants enter the food chain because reducing or eliminating them entirely from food is technologically infeasible or greatly increases the cost of producing that food. Some substances, such as pesticides and animal drugs, enter the food chain because they reduce the costs of producing food and thus reduce the cost of food to consumers, or increase the quality of foods. Still others improve various qualities of food, such as its taste, texture, visual appeal, and shelf life.

The risks to human health depend on how toxic the substance is (or the virulence of the micro-organism), how much is in particular foods, and how much of those foods an individual consumes. Even common and useful substances in food can be harmful if eaten in large enough quantities. However, the quantities of potentially harmful compounds that may be in foods are regulated and monitored to manage the risk from unsafe foods.

Researchers estimate from 6.5 million to 33 million Americans—or 3 to 14 percent of the population—become ill each year from micro-organisms in their food. An estimated 9,000 of these illnesses result in death, or 4 in 100,000 people. In contrast, the Environmental Protection
Tools in the Front Line of Food Safety

- Food labeling.
- Testing for microbes and chemical residues.
- Tolerance levels for food contaminants.
- Public education on thorough cooking and common hygiene practices.

Agency's worst case estimate is that pesticides in food potentially cause about 6,000 cases of cancer each year, or 2 in every 100,000 people. Most toxicologists and food scientists believe that microbial pathogens are a more serious hazard than chemical residues in the food supply.

Regulation Helps, But Is No Cure-All

This bulletin, focusing on food risks caused by microbial contamination and chemical residues, describes how scientific knowledge is growing and altering choices for policymakers, food producers, and consumers. It is based on the theory that consumers with adequate information can choose among different levels of safety in their diet by selecting a wide variety of foods with various taste, nutrition, price, and safety characteristics. For consumers to make informed decisions, they must know what is in particular foods and how those substances may affect their health. Consumers also must be able to weigh any benefits, such as a lower food price or desirable food qualities, against the risk of disease.

Without regulation and oversight, market incentives to provide risk information are often lacking. If sellers cannot recoup the extra costs of producing a safer product, they may not develop it.

Since the turn of the century, the Federal Government has joined State and local governments in controlling how much and what substances are allowed in foods. “Tolerances,” labeling, and food manufacturing process standards are the regulatory tools most often used by the Food and Drug Administration (FDA), the Environmental Protection Agency (EPA), and the U.S. Department of Agriculture’s (USDA) Food Safety and Inspection Service (FSIS). Tolerances are legal limits on the amount of a substance allowed in a commercially sold food. Food manufacturing process standards apply to sanitation and construction in packing plants, food processing establishments, groceries, and restaurants.

An effective regulatory program depends on enforcement practices. The incentives to comply depend heavily on the probability of detection and the penalty for not complying. Raising either the penalty or the detection rate will increase the costs of violation. Consequently, the economic incentives built into regulatory and enforcement programs are important policy considerations.

Public Education and Labeling Can Provide Safeguards

Other tools are occasionally used to increase food safety. Public education programs and health warnings telling consumers to cook raw pork thoroughly, for example, help to safeguard consumers against consuming the parasite in raw pork that causes trichinosis. The packages of many processed foods identify the ingredients used in preparation, such as colors, flavors, preservatives, artificial sweeteners, and other food additives. Although consumers have a choice about consuming products with identified additives, government plays an important role in ensuring that what is added is safe or poses small health risks and that the label is informative. Public education and labeling may enhance the safety of the food supply, but require consumers to take an active part in controlling health risks.

Risk Assessment Needed

The National Academy of Sciences (NAS) concluded in 1985 that current regulations for poultry were not aimed at detecting micro-organisms, the most important foodborne pathogens. Because testing all foods for all pathogens would dramatically raise the cost of producing food, NAS has recommended using a risk assessment approach; that is, to identify hazards, determine their importance, and set inspection priorities. The NAS report recommended that the meat and poultry inspection program be refocused to prioritize microbial and chemical testing compared with traditional visual inspection methods. FSIS is giving greater priority to microbial and chemical testing.

Microbial Contamination Is the Primary Offender

Foodborne disease can be caused by bacteria, parasites, viruses, fungi, and protozoa contaminating raw food. Inadequate cooking or food preservation will allow the pathogen to survive or multiply. Animal and seafood products (including dairy) are the major vehicles for foodborne disease.
Reported cases have increased over the last two decades for some diseases, such as salmonellosis (see chart). Changing food production and handling practices all along the food chain can change risks. Improved testing can identify more pathogenic organisms and trace them to foods and feedlots.

Bacterial contamination of food is the primary cause of foodborne disease. Severity of foodborne disease varies enormously and can be much more serious than just mild, brief illness (primarily diarrhea and vomiting for 1 or 2 days). The severity of a foodborne disease is determined by:

- the number and virulence of the organism,
- food composition,
- use of antacids (which lower the levels of stomach acids that kill microbes), and
- human susceptibility, which varies with age, presence of other disease, pregnancy, medications, nutrition, and immune system functioning.

Chronic diseases such as arthritis, central nervous system disorders, heart complications, blood poisoning, or kidney disease can occasionally be caused by common bacterial and parasitic diseases. An estimated 2-3 percent of foodborne disease cases have some kind of short- or long-term recurring aftereffects, according to Kvenberg and Archer.

Food processors typically use several techniques to control foodborne disease micro-organisms. These techniques include controlling food temperature during processing, making foods more acidic, and processing foods with a high sugar content, low water content, or high salt or nitrite content. Not even these barriers will correct all product abuses or be compatible with a particular food's taste.

New Food Habits May Cause Problems

New convenience foods such as precooked entrees for reheating at home or in restaurants pose new food safety problems. Vacuum packaging hinders the growth of spoilage microorganisms but may permit the production of botulism toxin at temperatures common in many commercial and home refrigerators. Some precooked foods may also be only minimally heated, eliminating the traditional last line of defense: thorough cooking immediately before eating. The widespread use of microwave ovens aggravates this problem because they can have cold spots allowing the bacteria and parasites to survive. The increasing diversity of the American diet also adds to the potential for microbial contamination. For example, fresh seafood, which is currently exempt from mandatory Federal inspection, has come under greater safety scrutiny as per capita consumption has increased. Foods never before imported into the United States may also contain microbes not normally found in the American food supply.

Microbial Risk Is Underestimated by Consumers

Consumers tend to underestimate the risk of microbial foodborne disease. Widely publicized USDA tests have shown that 35 percent of chickens are contaminated with Salmonella when they leave the slaughterhouse, according to a study by Green. Yet 16 percent of homemakers surveyed in 1974 indicated that they thought contamination was not at all likely, and another 47 percent thought contamination not too likely, according to Jones and Weimer. However, some of the risks are controllable with thorough cooking and better sanitation practices.
The Delaney Paradox in Regulating Pesticide Residues in Foods

All pesticides must receive Federal Government approval before entering the market. Before 1978, the Federal Government approved many pesticides when little was known about their chronic toxicity, such as their potential to cause cancer. Beginning in 1978, FIFRA imposed new requirements on what must be known about the toxicity of pesticides before EPA can approve their use on specific crops. Consequently, pesticides introduced in the last decade have faced tougher scrutiny.

But tougher scrutiny has not always resulted in a safer food supply, according to a 1987 report by the National Academy of Sciences. Although some new pesticides are significantly less carcinogenic and pose substantially fewer health risks than some pesticides already on the market, EPA has not always been able to register them under current law. Thus, older, potentially riskier pesticides continue to be used in some cases even though better ones could be available if approved. EPA denied the use of one fungicide on hops, for example, even though its oncogenic (tending to cause tumors, whether benign or malignant) risk, estimated at 1 in 100 million, was lower than that of currently used fungicides with a risk of 1 in 10,000.

New Tests Activate Delaney Clause

The Delaney Clause in Section 409 of the Federal Food, Drug, and Cosmetic Act prohibits any pesticide residue in processed foods if the pesticide is shown to cause cancer in humans or laboratory animals. The Delaney Clause was seldom applicable in the past because little data were available on the link between low levels of pesticide residues and tumors, or on the degree to which pesticide residues concentrated during food processing. But recent developments enable laboratory technicians to estimate even very small oncogenic risks and to detect very low levels of residues.

The Delaney Paradox

- Prohibits establishing a tolerance for a pesticide residue if that pesticide has been shown to induce cancer (but this standard applies only to processed foods), and
- Indirectly supports use of older, potentially riskier pesticides already approved, while disapproving newer, safer ones.

This new ability makes the Delaney Clause far more sweeping, creating a paradox of two different standards for assessing pesticide residues in food. These standards are the "zero cancer risk" standard of the Delaney Clause for processed foods and the "risk-benefit" standard of Section 408 of the Federal Food, Drug, and Cosmetic Act, which establishes tolerances for pesticide residues in raw commodities. Whether the residue concentrates before or during food processing, and where in the food production process pesticides are used, determines which standard applies. Yet there is no public health reason for making this distinction. The focus should be on the level of risk, not simply where it occurs in processing.

Double Standard Called Risky

The 1987 NAS study concluded that the double standard of applying the Delaney Clause only to pesticide residues that concentrate in processed foods but not to pesticide residues in raw foods results in greater cancer risks than a policy that allows tolerances for both raw and processed foods for pesticides that pose only a negligible risk. The study recognized that applying the Delaney Clause to pesticide residues in both processed and raw foods would eliminate 100 percent of the risk. But it concluded that a policy of allowing negligible risk would eliminate 98 percent of the oncogenic risk and yet have much less effect on the availability of pesticides and, hence, on food quantity, quality, and prices.

The costs of complying with the Delaney Clause as it is currently written could be very large. FIFRA requires EPA to reregister old pesticides as new data become available about their health effects, and the 1988 FIFRA amendments (P.L. 100-532) speed up the process. EPA called for new data in 1981, and at the time of the National Academy of Science report, EPA had data for 74 of the 289 pesticides currently registered. Of these 74, EPA has classified 53 as oncogens. These 53 compounds account for 90 percent of all fungicide use, 38 percent of all herbicide use, and 40 percent of all insecticide use. The situation is particularly acute for fungicides because few good substitutes are available or likely to be developed, according to NAS. The Delaney Clause may most affect fruits and vegetables because fungicides are widely used on these crops.

As an alternative to the Delaney Clause, EPA announced in October 1988 negligible risk criteria in setting tolerances for residues or carcinogenic pesticides in processed foods. While the new policy responds to the problems created by applying strict safety standards to new versus old pesticides, the policy does not completely address the paradox of different safety standards for pesticide residues in processed versus raw foods. Interest groups opposed to pesticides are likely to lobby against the policy.
Key to Enforcing Drug and Hormone Residue Levels: Make Sure Violation Costs More Than Compliance

Like pesticides, many approved animal drugs were registered for use based on safety evaluations now considered obsolete. As new data become available, the toxic potency of many drugs widely used to promote weight gain and prevent disease in livestock may be questioned. For example, the safety of sulfa drugs, widely used in swine and veal production, is under question. Sulfa drugs have long been known to cause allergic reactions in some sensitive individuals, and recent studies by FDA’s National Center for Toxicological Research indicate that sulfamethazine may be tumorigenic as well. Based on preliminary risk assessments, FDA has warned that it may lower the tolerance for sulfamethazine in swine or ban its use. Enforcing the correct method and level of use is important for growth hormones and all other animal drugs.

Of the animal drug residues in meat, milk, and eggs that USDA is responsible for monitoring, about 70 percent lack adequate, timely detection methods, according to a 1985 congressional report (Human Food Safety and the Regulation of Animal Drugs). Both public and private researchers are developing tests to detect animal drugs in food. USDA’s Food Safety and Inspection Service (FSIS) has made considerable progress in developing tests for detecting antibiotic and sulfa drug residues.

Sampling Techniques Used to Detect Violations

FSIS faces major constraints in detecting animals that violate the drug residue tolerances. Not every one of the millions of animals slaughtered each year can be individually tested. Instead, FSIS samples animals to estimate residues of different types of drugs. If the violation rate is very low and risks to human health are insignificant, no further action is taken. If the violation rate exceeds 1 percent, FSIS takes rigorous action and searches for the likely source of the violations. This effort requires costly and time-consuming research to identify the producers who are violating and why. If the producers can be pinpointed, FSIS, in conjunction with FDA, monitors them until the problem is eliminated.

But problems can be eliminated only if FSIS is able to make sure that violating the law costs more than complying with it. That is a problem because FSIS cannot simply fine violators. The agency can condemn and seize carcasses. FSIS can also initiate criminal procedures, but these actions based on detecting residues may be hampered by the complexity and slowness of tests requiring tissue samples. In some cases, by the time a violation of Federal drug residue standards is found, the carcass may have already been sold at retail and consumed.

Swine ID System Proposed

The marketing system makes it difficult to determine who produced the animal, and thus who is liable for any resulting problems. Identifying the producer of animals for slaughter is not mandatory. Thus, in some cases, neither slaughterhouses nor FSIS can inform producers who have violated the law nor can they apply followup testing to the future marketings of such producers. FSIS, in cooperation with USDA’s Animal and Plant Health Inspection Service (APHIS), has proposed a mandatory swine identification system. Such a system could lower the costs of identifying violators and shift the liability from processors to producers.

Costs of Foodborne Disease Affect All Sectors

The costs of foodborne disease fall upon those who become ill, their families and coworkers, their employers, food industries, and the public (see chart). Individuals’ costs include medical bills, time lost from work, and pain and inconvenience. Food industry costs include possible product recalls, plant closings and cleanup, higher premiums for product liability insurance, and reduced product demand if an outbreak of foodborne disease is highly publicized. Public costs include the public health sector costs of a disease surveillance system and investigating and eliminating disease outbreaks.

Medical costs and time lost from work for individuals are estimated in congressional testimony at around $1 billion a year for salmonellosis. Campylobacteriosis, a similar intestinal disease, also has medical and productivity costs of around $1 billion a year. Congenital toxoplasmosis, contracted from raw or undercooked pork, can lead to mental retardation in fetuses and is conservatively estimated to cost $215-$323 million a year. These partial estimates omit many other foodborne diseases. Individuals’ medical costs and productivity losses due to foodborne disease are several billion dollars a year.

While any regulatory program is costly, some benefit/cost analyses have estimated that some risk reduction programs would be less expensive than current medical expenses and productivity losses. However, the cost of eliminating all risks from the food supply would be prohibitively expensive. The level of risk reduction taxpayers and consumers are willing to pay for is a matter of public policy debate.
Foodborne disease: Exposure and costs

- **Food industry production**
  - Product recall
  - Plant closings and cleanup
  - Product liability cost
  - Reduced product demand

- **Household production**
  - Medical cost
  - Income or productivity loss
  - Pain and suffering
  - Leisure time cost
  - Child care cost
  - Risk aversion cost
  - Travel cost
  - Averting behavior cost

- **Public health regulations**
  - Disease surveillance cost
  - Cost of investigating outbreak
  - Cost of cleanup

**Food production, marketing & preparation**

**Presence of a hazard in food**

**Exposure to a hazard via consumption of food**

**Incidence of damage**

- **Food industry**
- **Households**
- **Public health sector**

**Cost of damage**

- **Monetizable cost**
- **Nonmonetizable cost**

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1 In adding up costs, care must be taken to assure that product liability cost to firms is not already counted in the estimated pain and suffering cost to individuals.

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Better Testing Raises More Questions

Changes in what is known about toxic potency and presence of substances in foods, and the amount of those foods that people eat, have raised important questions about food safety policies. New technologies have helped pinpoint where in the food production process a problem occurs, thus enabling analysts to focus on control procedures at that part of the process. These new technologies are becoming the new tools for domestic and foreign industries and regulators.

If food is consumed before test results are available, the effects of regulation are limited. Tests completed in hours or in 1-2 days increase the likelihood of recalling a product before it leaves the plant and increase the amount of product likely to be recovered. Congress appropriated $2 million in 1989 to speed up the development of rapid tests to monitor microbes and chemicals in foods and related issues.

- Should the public make greater efforts to reduce foodborne pathogens? Answering this question requires knowledge about the technological capabilities, benefits, and costs of controlling foodborne pathogens and recognizing control measures in the home or retail markets.
- Does the ability to detect increasingly minute amounts of substances in foods mean that we should seek more flexible laws than the Delaney Clause? This question would be better answered if we knew that the Delaney Clause helped reduce cancer risks, the public health significance of the risk, and how it affects food production costs compared with other alternatives.
- If the use of labeling is expanded, should labels communicate risk information to the public? Such communication will depend on what we know about how people develop beliefs about food risk and how that affects their behavior.
- What can be done about public confusion in the face of rapidly increasing and sometimes conflicting information about the safety of specific foods? By understanding the tradeoffs, perhaps both consumers and policymakers can make better choices.

Some Bills Introduced into the 101st Congress (January-April 1989)

**The Kennedy (S. 722)/Waxman (H.R. 1725) bill** would eliminate the Delaney paradox by requiring that both fresh and processed fruits and vegetables meet the same negligible risk standards. However, the proposed risk standard is very tough, may be impractical, and will increase the cost of producing food. This bill would also expand pesticide residue regulations to include examining the health effects of inert ingredients and metabolites in pesticides, would require that identifiable population groups with special food consumption patterns be considered in calculating health effects which must meet a negligible risk standard, and would expedite revoking tolerances for pesticides if the negligible risk standard is violated. Public access to data in support of pesticide petitions would be required, and EPA would be permitted to charge fees to carry out its regulation of pesticides.

**The Sikorski bill** (H.R. 1508) would terminate the tolerance for daminozide (Alar) under the Federal Food, Drug, and Cosmetic Act to protect children from adverse health effects.

**The Dorgan bill** (H.R. 1387) would extend USDA's inspection programs to all commercial seafood destined for U.S. consumption.

**The Smith bill** (H.R. 604) would reestablish minimum inspection and processing standards for poultry by revoking all rules and regulations implemented after July 1, 1977.

**The Kolter bill** (H.R. 240) would require manufacturers of foods with nutritional claims or for special dietary uses to maintain a toll-free telephone line for inquiries.
References


For Additional Information...

Contact Tanya Roberts, agricultural economist with Commodity Economics Division, Economic Research Service, U.S. Department of Agriculture, Room 1108, 1301 New York Avenue NW, Washington, DC 20005-4788 (phone 202-786-1864). Or call Eileen van Ravenswaay, professor of agricultural economics at Michigan State University, (phone 517-353-8628) and a member of the National Academy of Sciences committee that wrote Regulating Pesticide Residues in Food: The Delaney Paradox.

For general information on food safety issues, call the USDA Meat and Poultry Hotline, 1-800-535-4555.

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